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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/836,017	04/17/2001	Elisabeth Lacy Belden	P-9312	6994
27581	7590	09/08/2004	EXAMINER	
MEDTRONIC, INC. 710 MEDTRONIC PARKWAY NE MS-LC340 MINNEAPOLIS, MN 55432-5604			ODLAND, KATHRYN P	
			ART UNIT	PAPER NUMBER
			3743	

DATE MAILED: 09/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/836,017	Applicant(s) BELDEN ET AL.	
	Examiner Kathryn Odland	Art Unit 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 August 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 39-79 is/are pending in the application.
- 4a) Of the above claim(s) 46-49, 51 and 54-79 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 39-45, 50, 52 and 53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/26/01</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Claims 54-62, 65 and 67 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on August 12, 2004.

### ***Specification***

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Since there are many systems for placing medical electrical leads a more descriptive title is requested

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claim 39 recites the limitation "the coupling member" in lines 5 and 6. There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

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only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 39-45, 50 and 53 are rejected under 35 U.S.C. 102(e) as being anticipated by Cragg in US Patent No. 6,315,789.

Regarding claim 39, Cragg discloses an electrode assembly delivery system (as recited in column 7) having an elongate delivery device (such as 18/70, 72 and associated components) including a proximal portion, an atraumatic distal portion (32) and an electrode retention member (via 22, 34, etc.) adapted to temporarily couple the electrode assembly to the delivery device, as recited in columns 14-17 and seen in figures 6-8. Further, Cragg discloses the proximal portion (30) extends proximal to the coupling member (such as 22, 34) and the atraumatic distal portion (32) extends distal to the coupling member. There is an elongate introducer (such as 18) including a lumen having a diameter sufficient to slideably engage the proximal portion of the delivery device (such as 70, 72) and further includes a distal tip adapted to dislodge the electrode assembly distally from the retention member when the proximal portion of the delivery device extends within the lumen of the introducer. The distal portion of the delivery device can extend distal to the introducer distal tip and the electrode assembly is mounted on the retention member, as recited in columns 14-17 and seen in figures 6-8.

Regarding claim 40, Cragg discloses that as applied to claim 39 as well as a delivery device that is steerable. Applicant has not recited structure that would establish steability that would define over that disclosed by Cragg.

Regarding claim 41, Cragg discloses that as applied to claim 39 as well as a delivery device that includes a deflection wire (54) coupled to a distal end of the atraumatic distal portion and extending to a proximal end of the delivery device.

Regarding claim 42, Cragg discloses that as applied to claim 39 as well as an atraumatic distal portion is that is shapeable. The scope of this claim is broad and it has not been established when in the manufacturing process that the device is shapeable. The claim does not require the tip to be bendable during use. Thus, the device of Cragg is shapeable and capable of being shaped.

Regarding claim 43, Cragg discloses that as applied to claim 39 as well as an electrode retention member (22, 34) that has an outer surface adapted to form a press fit with an inner surface of a tubular portion of the electrode assembly to temporarily couple the electrode assembly to the delivery device, as recited throughout the specification.

Regarding claim 44, Cragg discloses that as applied to claim 39 as well as an electrode retention member that is a polymeric plug, as recited in column 10, lines 40-60. Cragg discloses the use of polymers, and it can be considered a "plug."

Regarding claim 45, Cragg discloses that as applied to claim 39 as well as an electrode retention member that is capable of rotation when mounted upon the delivery system.

Regarding claim 50, Cragg discloses that as applied to claim 39 as well as an electrode assembly that would necessarily include an elongate lead extending proximally therefore and a diameter of the introducer lumen that is sufficient to slidably engage the lead, as recited in column 7.

Regarding claim 53, Cragg discloses that as applied to claim 39 as well as a distal tip of the introducer that is radioopaque, as recited in column 10, lines 40-60.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cragg in US Patent No. 6,315,789.

Regarding claim 52, Cragg discloses that as applied to claim 39. However, Cragg does not recite a distal tip of the introducer that includes a nesting taper to aid in alignment of the electrode assembly for dislodging the electrode assembly. On the other hand, the tip of Cragg can be considered an equivalent since the function of dislodging the electrode is equally performed.

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**Conclusion**

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure are as follows: US Patent No. 6,671,560; US Patent No. 6,625,496; US Patent No. 6,456,889; US Patent No. 6,408,213; US Patent No. 6,192,280; US Patent No. 5,593,433 and US 2003/0181966.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KO

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